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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,261

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Alain Richard

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CANADA

EXAMINER

NELSON, CHRISTINE L

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

09/29/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,261	<b>Applicant(s)</b> RICHARD ET AL.	
	<b>Examiner</b> CHRISTINE L. NELSON	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 15-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10-19-2004, 6-4-2010</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Callaway (US Patent 5, 649, 929).

Regarding Claim 1, Callaway discloses a method for determining a distal cut thickness and posterior cut thickness for a femur in a knee replacement operation, the method comprising: performing a tibial cut on a tibia (column 6, lines 13-15); performing soft tissue balancing based on a desired limb alignment (19-20); measuring an extension gap between the femur and the tibial cut while in extension (20-21); measuring a flexion gap between the femur and the tibial cut while in flexion (22-42); calculating a distal cut thickness and a posterior cut thickness for the femur using the extension gap and the flexion gap and taking into account a distal thickness and posterior thickness of a femoral implant (43-59); and performing a femoral cut according to the distal cut thickness and the posterior cut thickness (60-65).

Regarding Claim 2, Callaway discloses that the distal cut thickness and posterior cut thickness are calculated such that a post-cut gap from the tibia to the femur is equal in extension and in flexion (Column 7, lines 16-18).

Regarding Claim 3, Callaway discloses performing a tibial cut comprising obtaining a tibial cut that is substantially perpendicular to a mechanical axis of the limb (Column 1, lines 32-34).

Regarding Claim 5, Callaway discloses performing a femoral cut comprising obtaining a femoral cut that is substantially parallel to the tibial cut such that the extension gap and said flexion gap are substantially rectangular after the femoral cut has been done (Column 1, lines 61-64). The femoral cut is made parallel to the tibial cut, and if the flexion gap and extension gap are matched (Column 7, lines 16-18), then the arrangement will be substantially rectangular.

Regarding Claim 6, Callaway discloses taking into account a distal thickness and posterior thickness by selecting a femoral implant having a distal thickness and a posterior thickness such that a desired distal cut thickness and posterior cut thickness may be obtained (Column 3, lines 18-20).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Callaway in view of Johnson (US Patent Number 4,718,413).

Regarding Claim 4, Callaway discloses the invention substantially as claimed, but does not disclose that performing a tibial cut comprises using a positioning device to align the substantially perpendicular cut. Johnson teaches the use of a guide when making a cut in the tibia that is substantially perpendicular (column 4, paragraphs 2-4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the positioning device of Johnson when making the cut as

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disclosed in Callaway, as using a cutting guide or positioning device is old and well known in the art to help improve accuracy and stability during a cutting procedure.

Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callaway in view of Carson et al. (US 2003/0069591 A1).

Regarding Claims 7-14, Callaway discloses the invention substantially as claimed, but does not disclose creating a reference coordinate system in a computer aided surgery system for the femur and the tibia and registering the femur and the tibia to the reference coordinate system using tracking devices. Carson et al. discloses using a reference coordinate system in a computer aided surgery system for the femur and the tibia and registering the femur and the tibia to the reference coordinate system using tracking devices (page 1, [0002]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the computer aided technology as derived from Carson et. al. and applied to total knee arthroplasty with the known procedures of Callaway, as using a computer aided tracking system for measuring and analyzing distances, spacing, alignment, and cutting planes would help with the specificity of the procedures as outlined by Callaway and would provide improved surgeon feedback for decision making at the time of surgery. Callaway discloses use of a tensor device between the femur and the tibia (Figure 1, 1 and 2).

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Pappas (US Pat Number 5,735,904), Tuke et al. (US Pat Number 5,800,438), and Nuelle et al. (US Pat Number 6,022,377) all relate to the spacing and evaluating of gap elements relative to knee prostheses. Brousseau et al. (US Pat. Number 6,450,978 B1) relates to use of computer assisted tracking in surgery.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE L. NELSON whose telephone number is (571)270-5368. The examiner can normally be reached on Monday through Friday 7:30 to 5:00 - first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTINE L. NELSON/  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
Unit 3775



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